



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,253	11/19/2001	Rod Harbin	WHP 3001	8388

30868 7590 12/18/2003

KRAMER & AMADO, P.C.
2001 JEFFERSON DAVIS HWY
SUITE 1101
ARLINGTON, VA 22202

EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,253

Applicant(s)

HARBIN ET AL.

Examiner

Patricia A Patten

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-8 in the response dated 11/3/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 9-11 are hereby withdrawn as they are directed toward a non-elected invention.

Claims 1-8 were examined on the merits.

Claim Objections

Claims 1 and 4 are objected to because of the following informalities: Claims 1 and 4 both recite 'which is above a freezing point of the solution'. Because solutions typically freeze at one temperature, it is asked that 'a freezing point' be changed to 'the freezing point'.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 4-7 rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (US 4,451,569).

Kobayashi et al. (US 4,451,569) disclosed a method for storing reduced glutathione via extraction from bovine erythrocytes, added to a phosphate buffer solution (aqueous solution) at pH 7.0 to a protein concentration of 10 mg/ml and freeze dried at certain temperatures to determine activity retention of said protein solution along with sugar stabilizers (col.2, line 60-col.3, line 17, Tables 3 and 4). It is noted that each solution combined with each sugar stabilizer was freeze dried three times at three respective temperatures; 30, 20 and 4 °C.

Therefore, the predetermined amount of reduced glutathione (10mg/ml) present in a solution of pH 7.0 was freeze dried at 4 °C according to Kobayashi et al. The concentration of the disappearance of reduced glutathione, as indicated in claim 1, is an inherent property of the glutathione in the conditions as recited in the claims. In this

Art Unit: 1654

respect, because all of the limitations were taught by Kobayashi et al., the rate of reduced glutathione decay (GSH decay) is inherent to the environment surrounding GSH. Further, Table 3 indicates that only 4% of glutathione had been oxidized when combined with sucrose as a stabilizer over a 3 month period. On average, this is less than a 2% loss per month. Because Kobayashi et al. teach every limitation of the environment surrounding GSH as is claimed, Kobayashi et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (US 4,451,569). Claims 4 and 8 are drawn to wherein the freezing temperature is 5 °C.

The teachings of Kobayashi et al. (US 4,451,569) were discussed *supra*. Kobayashi et al. did not specifically teach wherein the freezing temperature of the glutathione was 5 °C.

One of ordinary skill in the art would have been motivated to have freeze dried the glutathione solution at 5 °C in order to create a stored glutathione solution with superior reduction retention ability. Kobyashi et al. clearly demonstrated that the glutathione solutions added to the sugar stabilizers were only within one percentage point difference when frozen from 20 - 4 °C in each respective experiment. Therefore, the ordinary artisan would have had a reasonable expectation that freeze drying the glutathione solution in the presence of a sugar stabilizer at 5 °C would have provided successful protection of glutathione almost analogous to freeze drying at 4 °C.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone

Art Unit: 1654

number for the organization where this application or proceeding is assigned is (703) 872-3906.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

12/03/03

Patricia A Patten
Examiner
Art Unit 1654

A handwritten signature in black ink, appearing to read "Patricia A. Patten", written in a cursive style.

PATRICIA PATTEN
PATENT EXAMINER